therefor. The Administrator need not accept a petition if any of the requirements prescribed in paragraph (e) of this section or requested pursuant to paragraph (f) of this section are lacking or are not clearly set forth as to be readily understood. If the petitioner desires, he may amend and resubmit the petition to meet the requirements of paragraphs (e) and (f) of this section.

(h) If a petition is granted or the Administrator, upon his own motion, proposes to add or delete substances as listed chemicals as set forth in paragraph (c) of this section, he shall issue and publish in the FEDERAL REGISTER a proposal to add or delete a substance as a listed chemical. The Administrator shall permit any interested person to file written comments regarding the proposal within 30 days of the date of publication of his order in the FEDERAL REGISTER. The Administrator will consider any comments filed by interested persons and publish a final rule in accordance with his decision in the matter.

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 48733, Sept. 26, 1991; 57 FR 43615, Sept. 22, 1992; 60 FR 19510, Apr. 19, 1995; 60 FR 32460, June 22, 1995; 62 FR 5917, Feb. 10, 1997; 65 FR 21647, Apr. 24, 2000; 65 FR 47316, Aug. 2, 2000; 66 FR 52675, Oct. 17, 2001]

§ 1310.03 Persons required to keep records and file reports.

(a) Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction as specified by §1310.04 and file reports as specified by §1310.05. However, a non-regulated person who acquires listed chemicals for internal consumption or ''end use'' and becomes a regulated person by virtue of infrequent or rare distribution of a listed chemical from inventory, shall not be required to maintain receipt records of listed chemicals under this section.

(b) Each regulated person who manufactures a List I or List II chemical shall file reports regarding such manufacture as specified in Section 1310.05.

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 8277, Feb. 28, 1991; 61 FR 14023, Mar. 29, 1996]

EFFECTIVE DATE NOTE: At 67 FR 14861, Mar. 28, 2002, §1310.03 was amended by adding paragraph (c), effective Apr. 29, 2002. For the convenience of the user, the added text follows:

§ 1310.03 Persons required to keep records and file reports.

* * * * *

(c) Each regulated person who engages in a transaction with a nonregulated person which involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals), and uses or attempts to use the Postal Service or any private or commercial carrier shall file monthly reports of each such transaction as specified in §1310.05 of this part.

§ 1310.04 Maintenance of records.

(a) Every record required to be kept subject to §1310.03 for a List I chemical, a tableting machine, or an encapsulating machine shall be kept by the regulated person for 2 years after the date of the transaction.

(b) Every record required to be kept subject to Section 1310.03 for List II chemical shall be kept by the regulated person for two years after the date of the transaction.

(c) A record under this section shall be kept at the regulated person's place of business where the transaction occurred, except that records may be kept at a single, central location of the regulated person if the regulated person has notified the Administration of the intention to do so. Written notification must be submitted by registered or certified mail, return receipt requested, to the Special Agent in Charge of the DEA Divisional Office for the area in which the records are required to be kept.

(d) The records required to be kept under this section shall be readily retrievable and available for inspection and copying by authorized employees of the Administration under the provisions of 21 U.S.C. 880.

(e) The regulated person with more than one place of business where records are required to be kept shall devise a system to detect any party purchasing from several individual locations of the regulated person thereby seeking to avoid the application of the cumulative threshold or evading the requirements of the Act.

(f) For those listed chemicals for which thresholds have been established, the quantitative threshold or the cumulative amount for multiple transactions within a calendar month, to be utilized in determining whether a receipt, sale, importation or exportation is a regulated transaction is as follows:

(1) List I Chemicals:

Chemical	Threshold by base weight
(i) Anthranilic acid and its salts	30 kilograms.
(ii) Benzyl cyanide	1 kilogram.
(iii) Ergonovine and its salts	10 grams.
(iv) Ergotamine and its salts	20 grams.
(v) N-Acetylanthranilic acid and its salts	40 kilograms
(vi) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers	2.5 kilograms.
(vii) Phenylacetic acid and its salts	1 kilogram.
(viii) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers	2.5 kilograms.
(ix) Piperidine and its salts	500 grams.
(x) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers	1 kilogram
(xi) 3, 4-Methylenedioxyphenyl-2-propanone	4 kilograms.
(xii) Methylamine and its salts	1 kilogram.
(xiii) Ethylamine and its salts	1 kilogram.
(xiv) Propionic anhydride	1 gram.
(xv) Isosafrole	4 kilograms.
(xvi) Safrole	4 kilograms.
(xvii) Piperonal	4 kilograms.
(xviii) N-Methylephedrine, its salts, optical isomers, and salts of optical isomers	1 kilogram.
(xix) N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers	1 kilogram.
(xx) Hydriotic acid (57%)	1.7 kilograms (or 1 liter by volume).
(xxi) Benzaldehyde	4 Kilograms.
(xxii) Nitroethane	2.5 Kilograms.

(2) List II Chemicals:

(i) Imports and Exports

Chemical	Threshold by volume	Threshold by weight
(A) Acetic anhydride	250 gallons	1,023 kilograms.
(B) Acetone	500 gallons	1,500 kilograms.
(C) Benzyl chloride	N/A	4 kilograms.
(D) Ethyl ether	500 gallons	1,364 kilograms.
(E) Potassium permanganate	N/A	500 kilograms.
(F) 2-Butanone (MEK)	500 gallons	1,455 kilograms.
(G) Toluene	500 gallons	1,591 kilograms.

(ii) Domestic Sales

Chemical	Threshold by volume	Threshold by weight
(A) Acetic anhydride	250 gallons	1,023 kilograms.
(B) Acetone	50 gallons	150 kilograms.
(C) Benzyl chloride	N/A	1 kilogram.
(D) Ethyl ether	50 gallons	135.8 kilograms.
(E) Potassium permanganate	N/A	55 kilograms.
(F) 2-Butanone (MEK)	50 gallons	145 kilograms.
(G) Toluene	50 gallons	159 kilograms.
(H) Iodine	N/A	0.4 kilograms.
(I) Anhydrous Hydrogen chloride	N/A	0.0 kilograms.

(iii) The cumulative threshold is not applicable to domestic sales of Acetone, 2-Butanone (MEK), and Toluene.

(iv) Exports, Transshipments and International Transactions to Designated Countries as Set Forth in §1310.08(b).

Chemical	Threshold by volume	Threshold by weight
(A) Hydrochloric acid	50 gallons	

Chemical	Threshold by volume	Threshold by weight
(1) Anhydrous Hydrogen chloride.	.....	27 kilograms.
(B) Sulfuric acid	50 gallons	

(v) Export and International Transactions to Designated Countries, and Importations for Transshipment or Transfer to Designated Countries

Chemical	Threshold by volume	Threshold by weight
(A) Methyl Isobutyl Ketone (MIBK).	500 gallons	1523 kilograms.
(B) Reserved.		

(g) For listed chemicals for which no thresholds have been established, the size of the transaction is not a factor in determining whether the transaction meets the definition of a regulated transaction as set forth in §1310.01(f). All such transactions, regardless of size, are subject to recordkeeping and reporting requirements as set forth in this part 1310 and notification provisions as set forth in part 1313 of this chapter.

(1) Listed Chemicals For Which No Thresholds Have Been Established:

(i) Ephedrine, its salts, optical isomers, and salts of optical isomers

(ii) Red phosphorus

(iii) White phosphorus (Other names: Yellow Phosphorus)

(iv) Hypophosphorous acid and its salts

(2) [Reserved]

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 48733, Sept. 26, 1991; 57 FR 43615, Sept. 22, 1992; 59 FR 51367, Oct. 11, 1994; 60 FR 19510, Apr. 19, 1995; 60 FR 32460, June 22, 1995; 60 FR 42436, Aug. 16, 1995; 62 FR 5917, Feb. 10, 1997; 65 FR 47316, Aug. 2, 2000; 66 FR 52675, Oct. 17, 2001]

EFFECTIVE DATE NOTE: At 67 FR 14861, Mar. 28, 2002, §1310.04 was amended by removing paragraph (g) and revising paragraph (f)(1), effective Apr. 29, 2002. For the convenience of the user, the revised text follows:

§ 1310.04 Maintenance of records.

* * * * *

(f) * * *

(1) List I chemicals:

(i) Except as provided in paragraph (f)(1)(ii) of this section, the following thresholds have been established for List I chemicals.

Chemical	Threshold by base weight
(A) Anthranilic acid, its esters, and its salts	30 kilograms.
(B) Benzyl cyanide	1 kilogram.
(C) Ephedrine, its salts, optical isomers, and salts of optical isomers.	No threshold. All transactions regulated.
(D) Ergonovine and its salts	10 grams.
(E) Ergotamine and its salts	20 grams.
(F) N-Acetylanthranilic acid, its esters, and its salts.	40 kilograms.
(G) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	2.5 kilograms.
(H) Phenylacetic acid, its esters, and its salts.	1 kilogram.
(I) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.	2.5 kilograms.
(J) Piperidine and its salts	500 grams.
(K) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.	1 kilogram.
(L) 3,4–Methylenedioxyphenyl-2-propanone	4 kilograms.
(M) Methylamine and its salts	1 kilogram.
(N) Ethylamine and its salts	1 kilogram.
(O) Propionic anhydride	1 gram.
(P) Isosafrole	4 kilograms.
(Q) Safrole	4 kilograms.
(R) Piperonal	4 kilograms.
(S) N-Methylephedrine, its salts, optical isomers, and salts of optical isomers (N-Methylephedrine).	1 kilogram.
(T) N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers.	1 kilogram.
(U) Hydriodic Acid	1.7 kilograms (or 1 liter by volume).
(V) Benzaldehyde	4 kilograms.
(W) Nitroethane	2.5 kilograms.

(ii) Notwithstanding the thresholds established in paragraph (f)(1)(i) of this section, the following thresholds will apply for the following List I chemicals that are contained in drug products that are regulated pursuant to §1300.02(b)(28)(i)(D) of this chapter (thresholds for retail distributors and distributors required to report under §1310.03(c) of this part are for a single transaction; the cumulative threshold provision does not apply. All other distributions are subject to the cumulative threshold provision.):

Chemical	Threshold by weight
(A) Ephedrine, its salts, optical isomers, and salts of optical isomers as the sole therapeutically significant medicinal ingredient.	No threshold. All transactions regulated.
(B) Ephedrine, its salts, optical isomers, and salts of optical isomers in combination with therapeutically significant amounts of another medicinal ingredient:	
(1) Distributions by retail distributors	24 grams.
(2) Distributions by persons required to report under §1310.03(c) of this part.	24 grams.
(3) All other domestic distributions (other than paragraphs (f)(1)(ii)(B) (1) and (2) of this section).	1 kilogram.
(4) Imports and Exports	1 kilogram
(C) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers (other than ordinary over-the-counter products):	
(1) Distributions by retail distributors	24 grams.

Chemical	Threshold by weight
(2) Distributions by persons required to report under §1310.03(c) of this part.	24 grams.
(3) All other domestic distributions, (other than paragraphs (f)(1)(ii)(C) (1) and (2) of this section).	1 kilogram.
(4) Imports and Exports	1 kilogram.
(D) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers (ordinary over-the-counter products):	
(1) Distributions by retail distributors	Exempt.
(2) Distributions by persons required to report under §1310.03(c) of this part.	24 grams.
(3) All other domestic distributions (other than paragraphs (f)(1)(ii)(D) (1) and (2) of this section).	1 kilogram.
(4) Imports and Exports	1 kilogram.
(E) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers (other than ordinary over-the-counter products):	
(1) Distributions by retail distributors	24 grams.
(2) Distributions by persons required to report under § 1310.03(c) of this part.	24 grams.
(3) All other domestic distributions (other than paragraphs (f)(1)(ii)(E) (1) and (2) of this section).	2.5 kilograms.
(4) Imports and Exports	2.5 kilograms.
(F) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers (ordinary over-the-counter products):	
(1) Distributions by retail distributors	Exempt.
(2) Distributions by persons required to report under §1310.03(c) of this part.	24 grams.
(3) All other domestic distributions (other than paragraphs (f)(1)(ii)(F) (1) and (2) of this section).	2.5 kilograms.
(4) Imports and Exports	2.5 kilograms.

§ 1310.05 Reports.

(a) Each regulated person shall report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, as follows:

(1) Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this part.

(2) Any proposed regulated transaction with a person whose description or other identifying characteristic the Administration has previously furnished to the regulated person.

(3) Any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person. The regulated person responsible for reporting a loss in-transit is the supplier.

(4) Any domestic regulated transaction in a tableting machine or an encapsulating machine.

(b) Each report submitted pursuant to paragraph (a) of this section shall, whenever possible, be made orally to the DEA Divisional Office for the area in which the regulated person making the report is located at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved and as much in advance of the conclusion of the transaction as possible. Written reports of transactions listed in paragraphs (a)(1), (a)(3) and (a)(4) of this section will subsequently be filed as set forth in §1310.06 within 15 days after the regulated person becomes aware of the circumstances of the event. A transaction may not be completed with a person whose description or identifying characteristic has previously been furnished to the regulated person by the Administration unless the transaction is approved by the Administration.

(c) Each regulated person who imports or exports a tableting machine, or encapsulation machine, shall file a report (not a 486) of such importation or exportation with the Administration at the following address on or before the date of importation or exportation: Drug Enforcement Administration, P.O. Box 28346, Washington, DC 20038. In order to facilitate the importation or exportation of any tableting machine or encapsulating machine and implement the purpose of the Act, regulated persons may wish to report to the Administration as far in advance as possible. A copy of the report may be transmitted directly to the Drug Enforcement Administration through electronic facsimile media. Any tableting machine or encapsulating machine may be imported or exported if that machine is needed for medical, commercial, scientific, or other legitimate uses. However, an importation or exportation of a tableting machine or encapsulating machine may not be completed with a person whose description or identifying characteristic has previously been furnished to the regulated person by the Administration unless the transaction is approved by the Administration.